

NOV 02 2005

**REMARKS**

Claims 1-34 are presently pending in the case. Claims 13 and 21-26 have been withdrawn from consideration.

Reconsideration of the present case in view of the remarks herein is requested.

**Restriction**

Applicant affirms the provisional election of the embodiment of Figures 1 and 2. Claims 13 and 21-26 have been withdrawn from consideration only until the generic claim from which they depend is indicated to be allowable.

**Claim rejections under 35 USC 103(a)**

The Examiner rejected claims 1-12, 14-20, and 27-34 under 35 USC 103(a) as being unpatentable over U.S. Patent 5,921,236 to Ohki et al (hereinafter Ohki et al) in view of PCT Application WO 02/083220 to Edwards et al (hereinafter Edwards et al). The rejection is traversed.

Ohki et al does not render claim 1, for example, unpatentable. Claim 1 is to an aerosolization apparatus comprising, inter alia, a puncturing mechanism comprising an alignment guide, wherein the alignment guide comprises a surface adapted to contact a capsule and wherein at least a portion of the surface is sloped at an angle which is less than 55 degrees relative to the longitudinal axis of the capsule. Ohki et al does not disclose a surface that is sloped as claimed. Therefore, Ohki et al does not render claim 1 unpatentable.

Claim 1 is also not rendered unpatentable by Ohki et al and Edwards et al. Edwards et al also does not teach or suggest an alignment guide with at least a portion of the surface sloped at an angle which is less than 55 degrees relative to the longitudinal axis of the capsule. Edwards et al in this regard is discussed in Applicant's specification on page 8, lines 23-25. As can be seen from viewing Applicant's Figure 1B in conjunction with the discussion on page 8 lines 23-25, the device disclosed in Edwards et al has a surface that has an angle, a, less than 33 degrees. Since angle a is less than 33 degrees, the angle relative to the longitudinal

axis of the capsule (angle b) must be greater than 57 degrees. Since 57 degrees is not less than 55 degrees, Edwards et al does not teach the feature positively set forth in Applicant's claim 1. Therefore, claim 1 is not rendered unpatentable by Ohki et al and Edwards et al.

Applicant requests withdrawal of the rejection of claim 1 and claims 2-19 depending therefrom.

Independent claim 20 is also not rendered unpatentable by Ohki et al and Edwards et al. Claim 20 is to an aerosolization apparatus comprising, inter alia, a puncturing mechanism comprising an alignment guide, wherein the alignment guide comprises a surface adapted to contact a capsule and wherein the surface comprises one or more protrusions for contacting the capsule. Neither Ohki et al nor Edwards et al disclose an alignment guide surface with protrusions, as claimed. Therefore, Ohki et al and Edwards et al do not render claim 20 or depending claims 21-28 unpatentable.

Claim 29 is not rendered unpatentable by Ohki et al and Edwards et al either. Claim 29 is to a method of providing access to an aerosolizable pharmaceutical formulation, the method comprising, inter alia, contacting a capsule with the surface of an alignment guide, the surface being sloped at an angle which is less than 55 degrees relative to the longitudinal axis of the capsule. Ohki et al and Edwards et al do not teach or suggest at least this feature, as discussed above. Thus, claim 29 is not rendered unpatentable by Ohki et al and Edwards et al. Claim 30 depends from claim 29 and is also not rendered unpatentable by Ohki et al and Edwards et al.

In addition, claim 31 is not rendered unpatentable by Ohki et al and Edwards et al. Claim 31 is to a method of providing access to an aerosolizable pharmaceutical formulation, the method comprising, inter alia, contacting a capsule with the surface of an alignment guide, the surface comprising one or more protrusions for contacting the capsule. Ohki et al and Edwards et al do not teach or suggest this feature, as discussed above. Therefore, claim 31 and claim 32 which depends therefrom are not rendered unpatentable by Ohki et al and Edwards et al.

Ohki et al and Edwards et al also do not render claim 33 unpatentable. Claim 33 is to a method of aerosolizing a pharmaceutical formulation, the method comprising, inter alia, contacting the capsule with the surface of an alignment guide, the surface being sloped at an angle which is less than 55 degrees relative to the longitudinal axis of the capsule and/or having

one or more protrusions for contacting the capsule. As discussed above, Ohki et al and Edwards et al do not teach or suggest either of these features. Therefore claim 33 is not rendered unpatentable by Ohki et al and Edwards et al. Claim 34 depends from claim 33 and is also not rendered unpatentable by Ohki et al and Edwards et al.


**Conclusion**

The claims are allowable for the reasons given above. Thus, the Examiner is respectfully requested to reconsider the present rejections and allow the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

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Dated: 01 NOV 2005

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